1 2 3	Dan Lawton (State Bar No. 127342) dan@lawtonlaw.com Joseph C. Kracht (State Bar No. 228507) joe@lawtonlaw.com LAWTON LAW FIRM
4 5 6 7	Emerald Plaza 402 West Broadway, Suite 1330 San Diego, CA 92101 (619) 595-1370 (619) 595-1520 (Telefacsimile Number) www.lawtonlaw.com
8	Attorneys for Plaintiff Imprimis Pharmaceuticals, Inc.
10	IN THE UNITED STATES DISTRICT COURT
11	FOR THE SOUTHERN DISTRICT OF CALIFORNIA
12 13 14 15 16 17 18 19 20	IMPRIMIS PHARMACEUTICALS, INC., a Delaware corporation, Plaintiff, v. OCULAR SCIENCE, INC., a California corporation; and DOES 1 through 20, Defendants. Case No. '16CV0296 LAB WVG COMPLAINT FOR DAMAGES AND OTHER RELIEF FOR TRADEMARK INFRINGEMENT AND OTHER TORTS
21	Pursuant to Fed. R. Civ. P. 8(a), plaintiff Imprimis Pharmaceuticals, Inc.
22	("plaintiff" or "Imprimis"), hereby files this complaint, and avers the following:
23	<u>OVERVIEW</u>
24	This is a civil action in which Imprimis seeks, <i>inter alia</i> , damages and other relief
25	for trademark infringement and unfair competition.
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JURISDICTION AND VENUE

- 1. This action arises under the laws of the United States, Title 15 of the United States Code, and 28 U.S.C. § 2201 and Fed. R. Civ. P. 57.
- 2. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a) and (b), 1367, and 2201.
- 3. Venue is proper in this judicial district under pertinent law, including, *inter alia*, 28 U.S.C. §§ 1391(b), (c).

THE PARTIES

- 4. Imprimis is a corporation organized and existing under the laws of the State of Delaware and has as its principal place of business and is doing business in the State of California.
- 5. Defendant Ocular Science, Inc., is a corporation organized and existing under the laws of the State of California and has as its principal place of business and is doing business in the State of California. It is sometimes referred to hereinafter as "Ocular Science" or "defendant."
- 6. The true names and capacities, whether individual, corporate, associate, representative or otherwise, of defendants Does 1 through 20, inclusive, are unknown to Imprimis, who therefore sues them by such fictitious names. Imprimis will seek leave to amend this complaint to show the true names and capacities of said defendants when they are ascertained. Imprimis is informed and believes, and thereupon alleges, that each of the defendants named as a Doe, along with the named defendants, is responsible in some manner for the occurrences herein alleged, and that Imprimis' injuries herein alleged were legally or proximately caused by said defendants. Wherever it is alleged that any act or omission was also done or committed by any specifically named defendant, or by defendants generally, Imprimis intends thereby to allege, and does allege, that the same act or omission was also done and committed by each and every defendant named as a Doe, and each named defendant, both separately and in concert or conspiracy with the named defendants.

7. At all times mentioned herein, defendants, and each of them, were the agents, servants, co-conspirators, or employees of one another, and the acts and omissions herein alleged were done or suffered by them, acting individually and through or by their alleged capacity, within the scope of their authority. Each of the defendants aided and abetted and rendered substantial assistance in the accomplishment of the acts complained of herein. In taking the actions, as particularized herein, to aid and abet and substantially assist in the commission of the misconduct complained of, each defendant acted with an awareness of his, its or its primary wrongdoing and realized that his, its or its conduct would substantially assist in the accomplishment of that misconduct and was aware of his, its or its overall contribution to, and furtherance of the conspiracy, common enterprise, and common course of conduct. Defendants' acts of aiding and abetting included, *inter alia*, all of the acts each defendant is alleged to have committed in furtherance of the conspiracy, common enterprise, and common course of conduct complained of herein.

BACKGROUND FACTS

8. In 2012 and 2014, respectively, applications nos. US 14/461,242 (priority to July 22, 2013) and 14/227,819 (priority to July 22, 2013) were filed with the U.S. Patent and Trademark Office. Generally, these patent applications describe inventions for novel slow-releasing ophthalmic compositions containing triamcinolone acetate, moxifloxacin hydrochloride, triamcinolone acetate, and vancomycin and uses thereof in the treatment of acute infections of the eye and compositions for intraocular injection of therapeutically effective quantities of anti-bacterial and anti-inflammatory agents, as well as methods for fabricating the compositions and for using them in intraocular injections. Imprimis is the assignee of the rights asserted in these applications. The claimed inventions are highly useful for "dropless" cataract surgery, something that is attractive to both eye surgeons and patients who suffer from cataracts. Imprimis' applications for patents published on October 30, 2014, and January 22, 2015, respectively.

- 9. Imprimis is the owner of the following trademarks: GO DROPLESS! (U.S. Serial No. 96143543), GO DROPLESS! Logo (U.S. Serial No. 86143553), LESSDROPS (U.S. Serial No. 86497791), DROPLESS CATARACT THERAPY (U.S. Serial No. 86497090), and DROPLESS THERAPY (U.S. Serial No. 86497100) (collectively hereinafter referred to as the "Imprimis marks"). As a matter of law, Imprimis has the exclusive rights to the use of said marks and said trademarks are valid, subsisting, and in full force and effect.
- and promotion of its products and has spent large sums of money to promote and advertise its products under the Imprimis marks. As a consequence, the Imprimis marks have become identified, in the United States and throughout the world, as signifying novel slow-releasing ophthalmic compositions containing triamcinolone acetate, moxifloxacin hydrochloride, triamcinolone acetate, and vancomycin and uses thereof in the treatment of acute infections of the eye and compositions for intraocular injection of therapeutically effective quantities of anti-bacterial and anti-inflammatory agents, as well as methods for fabricating the compositions and for using them in intraocular injections. These agents and methods are highly useful for "dropless" cataract surgery, something that is attractive to both eye surgeons and patients who suffer from cataracts.
- 11. Since 2014, Imprimis has sold more than \$4.3 million worth of products under the Imprimis marks in North America alone. Since that same year, Imprimis has spent more than \$4 million in the United States advertising and promoting the Imprimis marks. In addition, over fifty (50) articles concerning Imprimis products and mentioning the Imprimis marks have appeared recently in major ophthalmic surgery center-targeted trade publications.
- 12. The products manufactured, distributed and sold by Imprimis bearing the Imprimis marks have become well known in the United States and throughout the

world both by users of such products and the public generally as being products of high quality having their exclusive origin with Imprimis.

13. As a result of the recognized quality of Imprimis' products and its extensive advertising and promotion of the Imprimis marks in the United States and throughout the world, Imprimis has developed an acquired valuable good will that is directly associated with the Imprimis marks.

DEFENDANTS' WRONGFUL COURSE OF CONDUCT: MARKETING IN VIOLATION OF FEDERAL LAW

- 14. The U.S. Food, Drug and Cosmetic Act ("FDCA") places heavy restrictions on commercial advertising and marketing of drugs and specifically restricts the commercial advertising and marketing of compounded drug formulations. In order for a company to make public claims of the effectiveness of a drug, the drug in question must be approved of by the U.S. Food and Drug Administration (the "FDA"). If the drug is not approved of by the FDA, or is a compounded drug formulation, a company is restricted on their ability to make public representations and claims on the effectiveness of these drug.
- 15. The FDA has publicly stated, "Federal law generally requires that prescription drugs in the U.S. be shown to be both safe and effective prior to marketing (emphasis added)...Furthermore, FDA's review of the applicant's labeling insures that health care professionals and patients have the information necessary to understand a drug product's risks and its safe and effective use...The Agency has serious concerns that drugs marketed without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling. Physicians and other healthcare practitioners, along with consumers, cannot assume that all marketed drugs have been found by the FDA to be safe and effective. For a variety of historical reasons, some drugs, mostly older products, continue to be marketed illegally in the U.S. without required FDA approval...The lack of evidence

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http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcement activities by fda/selected enforcement actions on unapproved drugs/default. htm.

demonstrating that these unapproved drugs are safe and effective is a significant public health concern.¹

- 16. These laws recognize that the advertising of non-approved FDA drugs is deceptive because it conveys to consumers, based upon existing FDA rules and regulations, the net impression that such drugs: (i) are in fact approved of by the FDA, (ii) make only positive contributions to a patient's health; and (iii) do not pose any negative health related side effects.
- Imprimis is aware of FDA and FDCA restrictions on advertising and 17. marketing drugs and follows such restrictions and guidelines, severely limiting the marketing disclosures Imprimis makes to its customers and the public in general.
- 18. Ocular Science is currently publicly marketing non-FDA approved postoperative compounded formulations including drop formulas and an injection formula for administration during surgery. These include: (i) Pred-Moxi (prednisolone sodium phosphate and moxifloxacin hydrochloride) ("Pred-Moxi"), a four dose per day eye drop combining a steroid and an antibiotic to reduce pain and inflammation in the eye; (ii) Pred-Moxi-Ketor (prednisolone sodium phosphate, moxifloxacin hydrochloride and ketorolac tromethamine) ("Pred-Moxi-Ketor"), a four dose per day eye drop that combines a steroid, an antibiotic, and a non-steroidal anti-inflammatory; (iii) Pred-Ketor (prednisolone sodium phosphate and ketorolac tromethamine) ("Pred-Ketor"), a four dose per day drop that combines a steroid and a non-steroidal anti-inflammatory; (iv) Pred-Levo (prednisolone sodium phosphate and levofloxacin) ("Pred-Levo"), a two dose per day drop that combines a steroid and an antibiotic, and (v) Dex-Moxi (dexamethasone ophthalmic and moxifloxacin hydrochloride) ("Dex-Moxi"), a formula intended for intraocular injection into the anterior chamber of the eye. (Pred-Moxi, Pred-Moxi-Ketor, Pred-Ketor, Pred-Levo and Dex-Moxi may be referred to hereinafter collectively as the "Ocular Science Formulations").

- 19. While the <u>sale</u> of compounded drugs in general do not need to be approved of by the FDA (they are governed by state laws, rules and regulations), Ocular Science has made, and continues to make, illegal claims in their <u>advertising</u> and <u>marketing</u> of the Ocular Science Formulations in violation of the FDCA and California laws that govern such advertising and marketing. These claims, disclosed in Ocular Science's online website (www.ocularscience.com) and outlined in *Exhibit A* attached hereto, include, but are not limited to:
- (i) In the coming year, they are set to release an Amniotic Drop, revolutionizing the patient experience and <u>reducing dry eye and inflammation</u> through exceptional post-operative care (*Exhibit A*, Page 1)(*emphasis added*).
- (ii) We created and optimized DROPLET to help physicians <u>achieve the best</u> <u>patient outcomes</u> at the lowest patient cost (*Exhibit A*, Page 2)(*emphasis added*).
- (iii) These formulas *promote rapid healing* and are engineered with patient adherence in mind. (*Exhibit* A, Page 2)(*emphasis added*).
- (iv) Our unique formulas require less effort from the patient and <u>lead to</u> <u>higher efficacy</u>. (**Exhibit A**, Page 2)(emphasis added).
- (v) Pred-Moxi is a four dose per day eye drop that combines a steroid and an antibiotic to <u>reduce pain and inflammation in the eye</u>. (**Exhibit** A, Page 2)(emphasis added).
- (vi) Read more about the <u>proven effectiveness</u> (**Exhibit** A, Page 2)(emphasis added).
- (vii) Read more about the <u>proven effectiveness</u> (*Exhibit A*, Page 4)(*emphasis added*).
- (viii) The formula is completely clear, allowing a patient to leave your office without the milkiness that typically occurs (Exhibit A, Page 4)(emphasis added).
- (ix) Our latest product, an amniotic eye drop, is the <u>first of its kind for dry</u> <u>eye and wound healing</u>. (**Exhibit A**, Page 5)(emphasis added)

- (x) This drop can be safely stored in a home freezer <u>while retaining its</u> <u>efficacy</u>. (**Exhibit** A, Page 5)(emphasis added).
- (xi) New research indicates that secretions from stem cells found in Ocular Science's amniotic fluid can *restore balance and calm this chronic inflammation*. (*Exhibit A*, Page 5)(*emphasis added*).
- (xii) Ocular Science's amniotic eye drops have over 100 cytokines, growth factors and anti-infmallatory [sp] molecules, including key mediators like thrombospondin-1(TSP-1), WNT 4, PGE2 and GDF11, which modulate and restore balance to tears. (Exhibit A, Page 5)(emphasis added).
- (xiii) Read more about the <u>proven effectiveness</u> (**Exhibit** A, Page 6)(emphasis added).
- 20. Ocular Science's promotion, marketing and advertising as outlined above is false and misleading, and part of an extensive promotional, marketing and advertising campaign designed to increase the sales of the Ocular Science Formulations. This campaign and these misrepresentations portray to consumers that the Ocular Science Formulations are in fact approved of by the FDA (which they are not), which in turn affects their decision in which products to purchase. Ocular Science's misrepresentations have and will continue to mislead consumers into believing incorrectly that the Ocular Science Formulations are FDA approved (which they are not). Meanwhile, Imprimis has and continues to abide by the FDCA and FDA guidelines and does not make such restricted and illegal claims, thus providing Ocular Science an unfair competitive advantage over Imprimis.

DEFENDANTS' WRONGFUL COURSE OF CONDUCT:

TRADEMARK INFRINGEMENT

- 21. Ocular Science is currently marketing the Ocular Science Formulations.
- 22. These Ocular Science Formulation products are "copycat" formulations. Ocular Science has been marketing them using the name DROPLET (as shown on its website). The name DROPLET is confusingly similar to Imprimis' marks (including

without limitation GO DROPLESS!, LESSDROPS, DROPLESS CATARACT THERAPY, and DROPLESS THERAPY. By use of it, Ocular Science has created confusion and harmed the reputation of Imprimis' inventions, to the result that some physicians who previously ordered from Imprimis (and who have monthly cataract cases in the hundreds) have stopped doing so. The confusion in the market includes the false belief that the goods Ocular Science is selling belong to, are sponsored by, or are affiliated with Imprimis.

FIRST CLAIM FOR RELIEF

(Infringement of Trademarks)

(Against All Defendants)

- 23. Imprimis realleges and incorporates by reference as though fully set forth in the preceding paragraphs 1 through 22.
- 24. Imprimis owns the Imprimis marks. Under common law, Imprimis has the exclusive right to the use of said mark and said marks are valid, subsisting, and in full force and effect.
- 25. Beginning in 2015, Ocular Science began selling a similar product under the name Dropless.
- 26. Ocular Science' use of the designation "DROPLET" has caused, and is likely to continue to cause, confusion on the part of those persons who purchase ophthalmic compositions containing triamcinolone acetate, moxifloxacin hydrochloride, triamcinolone acetate, and vancomycin for the purpose of treating infections of the eye and compositions and for intraocular injection of therapeutically effective quantities of anti-bacterial and anti-inflammatory agents. Such use has misled and deceived, and will continue to mislead and deceive, the public as to the source and sponsorship of Ocular Science's products.
- 27. Imprimis, however, not Ocular Science, is the senior user of the Imprimis marks, with an actual date of first use antedating that claimed by Ocular Science.

 Imprimis is entitled to use, in interstate commerce, its marks in the goods identified in

commerce and also on goods which, in the minds of the consuming public, are considered to be closely related to the goods listed in those registrations.

- 28. Ocular Science's continued use of the "DROPLET" mark based on its alleged date of first use is likely to cause confusion, deception, and mistake in the minds of the consuming public, all to the detriment of Imprimis, its trademark reputation, goodwill, and business.
- 29. For the foregoing reasons. Imprimis has been damaged by Ocular Science's allegation of trademark rights superior to those of Imprimis, and will continue to be damaged, unless this Court intervenes.
- 30. As the direct and proximate result of Ocular Science's wrongful acts, Imprimis has been damaged in an amount to be proven at trial.
- 31. The acts of infringement described above are willful, deliberate and in reckless disregard of Imprimis' rights. On this basis, Imprimis is entitled to an award of punitive damages in an amount sufficient to make an example of Ocular Science and to deter others from similar misconduct in the future.

SECOND CLAIM FOR RELIEF

(Common Law Unfair Competition)

(Against All Defendants)

- 32. Imprimis realleges and incorporates by reference as though fully set forth in the preceding paragraphs 1 through 31.
- 33. This claim for relief arises under the common law of trademarks and unfair competition.
- 34. The use of the "DROPLET" name and mark by defendants will lead to the erroneous belief that Ocular Science's products originate with, or are sponsored by, or are endorsed or licensed by Imprimis, or that Imprimis is somehow associated with the business or products of Ocular Science, thus enabling Ocular Science to misappropriate and unfairly trade upon Imprimis' valuable goodwill and the renown of its mark, and subjecting Imprimis' goodwill and reputation in the Imprimis marks

to the hazards and perils to Ocular Science's business activities (over which Imprimis

with it, that the products Ocular Science sells are those of Imprimis, and that Ocular Science is selling at the direction of Imprimis. In fact, none of these things is true.

- 43. The foregoing acts of Ocular Science constitute trademark and trade name infringement under the common law.
- 44. As a direct and proximate result of Ocular Science's infringements, Imprimis has suffered, and will continue to suffer, irreparable injury unless and until the Court enjoins Ocular Science from further infringements.

FIFTH CLAIM FOR RELIEF

(For Declaratory Relief under 28 U.S.C. § 2201)

(Against All Defendants)

- 45. Imprimis realleges and incorporates by reference as though fully set forth in the preceding paragraphs 1 through 44.
- 46. There exists an actual controversy between the parties as to their rights and liabilities vis-a-vis one another and with respect to the Ocular Science mark and the Imprimis marks.
- 47. Imprimis is entitled to a decree declaring the parties' rights and liabilities under the provisions of 28 U.S.C. § 2201.

SIXTH CLAIM FOR RELIEF

(For Injunctive Relief)

(Against All Defendants)

- 48. Imprimis realleges and incorporates by reference as though fully set forth in the preceding paragraphs 1 through 47.
- 49. By reason of Ocular Science's actions, Imprimis has been seriously and irreparably damaged, Imprimis' business reputation has been injured, and Imprimis has suffered dilution of the distinctive quality of its marks. Unless and until Ocular Science is restrained, Imprimis will continue to be so damaged until this action can proceed to final judgment.
 - 50. Ocular Science's wrongful conduct, unless and until enjoined by order of

this Court, will cause great and irreparable injury to Imprimis. The goodwill is established by Imprimis, and being tarnished by Ocular Science, is irreplaceable and cannot be remedied adequately by recovery of money damages.

- 51. Imprimis requests that this Court grant a temporary restraining order and preliminary and permanent injunctions enjoining Ocular Science and its agents, servants, and employees, and all persons acting under, in concert with, or for them from doing the following:
 - (i) from continuing the use of the infringements identified hereinabove;
- (ii) from using in connection with its business, except as expressly authorized by Imprimis, any reproduction or colorable imitation of the word "DROPLET";
- (iii) from making in any way whatsoever any statement or representation or performing any act likely to lead the public or individual members of the public to believe that Ocular Science is in any manner, directly or indirectly, associated or connected with, or licensed, authorized or approved by Imprimis; and
- (iv) from committing any other act which infringes on Imprimis' marks or constitutes unfair competition against Imprimis or its licensees.

PRAYER FOR RELIEF

WHEREFORE, Imprimis prays for relief as follows:

- A. That the Court award Imprimis such general and special damages as it has sustained by reason of Ocular Science's infringements and unfair competition according to proof at trial and that, because of the willful nature of said infringements, the Court enter judgment for Imprimis for those damages and for three times the amount of those damages pursuant to section 35 of the Lanham Act, 15 U.S.C. § 1117;
- B. For judgment that Ocular Science has violated section 32 of the Lanham Act, 15 U.S.C. § 1114;

marks or colorable imitations thereof;

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1	J. That the Court assess Ocular Science Imprimis' attorneys' fees and
2	award those fees to Imprimis pursuant to section 35 of the Lanham Act, 15 U.S.C. §
3	1117, given the willful nature of Ocular Science's infringements;
4	K. That the Court assess Ocular Science punitive damages because of the
5	willful nature of its infringements;
6	L. That Ocular Science be ordered to file with the Court and serve on
7	Imprimis' counsel, within thirty (30) days after service of any injunction(s) issued
8	herein, or within such other reasonable time as the Court shall direct, a report in
9	writing and under oath, setting forth in detail the manner in which Ocular Science has
10	complied with any such injunction(s);
11	M. That the Court assess pre-judgment and post-judgment interest and
12	costs of suit (including all disbursements and expenses of this action) against
13	defendants, and award such interest and costs to Imprimis; and
14	N. That Imprimis have such other and further relief as this Court may deer
15	just and proper.
16	Respectfully submitted,
17	Dated: February 3, 2016 LAWTON LAW FIRM
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19	By: <u>s/Dan Lawton</u> Dan Lawton
20	Attorneys for Plaintiff Imprimis Pharmaceuticals Inc.
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DEMAND FOR TRIAL BY JURY AND FOR SPEEDY HEARING Plaintiff hereby demands a trial by jury as to all issues triable by jury. Plaintiff also requests a speedy hearing of its claim for declaratory judgment pursuant to Fed. R. Civ. P. 57. Respectfully submitted. Dated: February 3, 2016 LAWTON LAW FIRM By: s/Dan Lawton Attorneys for Plaintiff Imprimis Pharmaceuticals,